REMARKS

The specification and claims have been carefully reviewed in the light of the Office Action to which this amendment is responsive. By this amendment, independent claim 11 has been amended to distinguish even more clearly over the prior art.

Claims 2-11 have been rejected as being obvious over Frigg et al. (5,180,382) in view of Grossberndt (4,544,313), and reconsideration of such rejection is respectfully requested. Applicant's invention is directed to a specialized bone screw having specially designed utility over the prior art. As brought out in the prior prosecution, Grossberndt is non-analogous art which neither relates to the field of bone screws, nor concerns similar problems. Indeed, Grossberndt relates to a screw for soft material, such as particle boards. While Frigg et al. relates to bone screws, it teaches away from applicant's invention.

The bone screw of the present invention has a threaded portion with a core and outside diameter that taper gradually and uniformly toward the tip to define threads of a constant height within a prescribed range and which are separated by a specifically defined concave profile for the particular application. In contrast, Frigg et al. discloses a bone screw with a completely different threaded configuration and size and which does not have a uniform taper. Indeed, Frigg et al. discloses a bone screw having two threaded sections 6, 7 of different diameters, separated by a "transitional area" 13 (*see* Fig. 1 and col. 2, lines 42-46). The "transitional area" defines a step that brings about a relatively sudden reduction in the screw diameter, which in turn, can create problems with use of the bone screw in certain applications, depending upon the site on the bone upon which the screw is inserted. In a first situation, as depicted in Fig. 1 in Appendix A attached hereto, the screw is inserted in a substantially middle portion of the bone, *i.e.,* about midway from the bone ends, and in a second situation, as depicted in Fig. 2 of Appendix A, the screw is inserted near or at an end of the bone.

In the first situation, the bone has, in section, two external, diametrically opposed layers of compact bone tissue and a central portion, which is substantially hollow. In that case, the load applied to a cantilever portion of the screw is counteracted by two forces, which are localized at the compact layers, the one where the screw diameter is larger and the other one where the screw diameter is shorter. Practically no counteraction is exerted by the central portion of the bone. In such situation, the profile of the threaded portion of the screw between the larger and the shorter diameter does not play a fundamental role.

In the second situation, however, the bone has only a very thin layer of compact bone tissue and a predominant inner portion of spongy tissue. The spongy tissue has an elasticity module E of about 0.3 GPa, whereas the compact bone tissue has an elasticity module E of about 17-20 GPa. In this situation, the entire bone counteracts the load, with a reacting force, which is evenly distributed along the entire thickness of the bone. In such case, the profile of the threaded portion of the screw plays a fundamental role and sudden changes of the screw diameter result in load peaks and loss of load. This is what happens with the screw according to Frigg et al., where there occurs the sudden transition from the major diameter of the screw to the minor diameter of the screw through the short conical transitional portion.

In contrast, with the screw according to the present application, there is a continuous and gradual transition from a major to a minor diameter, due to the conical profile, with constant conicity, of the threaded portion itself. As a consequence, the reaction to the load applied to the cantilever portion of the screw is provided by a counter-load which is evenly and continuously distributed, without load peaks or loss of load. Hence, it can be seen that when the bone screw of the present invention is used near the end of the bone, the distribution of counteracting forces the screw has enhanced load capacity and decreased invasiveness as compared to the screw profile of Frigg et al. Moreover, the constant taper and uniform thread size substantially enhances manufacturability of the screw, as compared to that of Frigg et al. which has multiple cylindrical sections of different diameter and a short conical transition section.

Hence, independent claim 11 is believed to clearly distinguish over the prior art. Moreover, even the combination of Frigg et al. and the non-analogous Grossberndt fails to result in the inventive bone screw as defined in claim 11. Neither reference discloses a single threaded section with uniformly tapered outside and core diameters having the specifically defined threads of constant height. In Grossberndt the height of the threads are not uniform (col. 2, lines 47-48); in Frigg et al. the threaded section does not have a constant taper; and in neither reference do the threads have the specifically defined proportions for the enhanced bone securement utility. The dependent claims are directed to further specific features of the invention, and for similar reasons, distinguish over the art.

In re Appln. of *DANIELE VENTURINI*
Application No. *09/937,941*

From the foregoing, it is believed that the claims as now presented all are directed to features which are neither disclosed nor suggested by the prior art so as to be in condition for allowance. Accordingly, an early action to that affect is respectfully requested.

Respectfully submitted,

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